SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MICROBIOLOGY DEVICES PANEL MEETING

MEDICAL DEVICES ADVISORY COMMITTEE

September 8, 2023
9:00 a.m. EST

Attendees

Chairperson

Barbara Van Der Pol, PhD, MPH
Professor of Medicine and Public Health
Division of Infectious Diseases
University of Alabama - Birmingham, AL

Voting Members

Ricardo M. La Hoz, MD, FACP, FAST, FIDSA
Director of Solid Transplant Infectious Diseases
Associate Professor of Medicine
Division of Infectious Diseases
University of Texas Southwestern Medical Center - Dallas, TX

Thomas A. Moore, MD, FACP, FIDSA
Clinical Professor of Medicine
Infectious Disease Physician
University of Kansas School of Medicine - Wichita, KS

Temporary Non-Voting Members

Cathy A. Petti, MD
Clinical Microbiologist
President and CEO
Health Spring Global, Inc. - Carson City, NV

Emily A. Blumberg, MD, FACP, FIDSA, FAST
Professor of Medicine
Director of Transplant Infections Diseases Department of Medicine
Infectious Disease Fellowship Program
University of Pennsylvania School of Medicine - Philadelphia, PA

Camille N. Kotton, MD, FIDSA, FAST
Clinical Director of Transplants and
Immunocompromised Host Infectious Diseases
Massachusetts General Hospital
Associate Professor at Harvard Medical School - Boston, MA

Angela M. Caliendo, MD, PhD, FIDSA, FAAM
Warren Alpert Foundation Professor
Executive Vice Chair of Medicine
Alpert Medical School of Brown University - Providence, RI

Marcus R. Pereira, MD, MPH
Associate Professor of Medicine
Medical Director of the Transplant Disease Program
Director of Clinical Services, Division of Infectious Diseases
Columbia University Medical Center - New York, NY

Valerie L. Ng, MD, PhD
Professor Emeritus of the Department of Laboratory Medicine
Laboratory Director, Laboratory Medicine and Pathology
Director, Transfusion Services
Lab Director and Chair of the Department of Alameda Health System
University of California, San Francisco - Alameda, CA

Nicolas A.H. Wentzensen, MD
Senior Investigator and Deputy Director of the
Clinical Genetics Branch at the National Cancer Institute
Head, Clinical Epidemiology Unit
Division of Cancer Epidemiology and Genetics - Bethesda, MD

Kathleen G. Beavis, MD
Professor of Pathology
University of Chicago - Chicago, IL

Gary W. Procop, MD
CEO American Board of Pathology
Professor of Pathology
Cleveland Clinic Lerner College of Medicine - Cleveland, OH

Charles Y. Chiu, MD, PhD
Professor in Laboratory Medicine and Infectious Diseases
University of California - San Francisco, CA

Industry Representative

Bradford M. Spring, MS
Head of Global Regulatory Policy and Intelligence at
Roche Diagnostics - Washington, DC

Consumer Representative

Roblena E. Walker, PhD
CEO of EMAGAHA, Inc.
Research Scientist - Mableton, GA

Patient Representative

Jennifer A. Schwartzott, MS - North Tonawanda, NY

FDA Participants

Timothy Stenzel, MD, PhD
Office Director
CDRH/OPEQ/OHTVII/DMD, FDA - Silver Spring, MD

Uwe Scherf, M.Sc., PhD
Division Director
CDRH/OPEQ/OHTVII/DMD, FDA - Silver Spring, MD

Kristian Roth, PhD
Deputy Division Director
CDRH/OPEQ/OHTVI/DMD, FDA - Silver Spring, MD

Designated Federal Officer

Candace Nalls
FDA - Silver Spring, MD

FDA Presenters

Timothy Stenzel, M.D., Ph.D.
Director, OHT7: Office of In Vitro Diagnostics, CDRH, FDA - Silver Spring, MD

Kristian Roth, Ph.D.
Deputy Director, Division of Microbiology Devices, OHT7, CDRH, FDA - Silver Spring, MD

CALL TO ORDER
INTRODUCTIONS

Dr. Van Der Pol called the meeting to order, announced that Panel members are trained in device law and regulation, and stated the day's agenda: to discuss and provide recommendations to FDA regarding topics related to in vitro diagnostic devices used in pandemic preparedness and response consistent with the requirements under Section 3302 of FDORA. She then prompted the Panel members to introduce themselves.

CONFLICT OF INTEREST STATEMENT

Ms. Candace Nalls, Designated Federal Officer, read the Conflict-of-Interest statement and announced the issue of a waiver to Dr. Angela Caliendo for stock holdings in the affected firms. She appointed Dr. Bradford Spring as the industry representative and Dr. Roblena Walker and Ms. Jennifer Schwartzott as temporary non-voting members.

FDA PRESENTATION: IVDs Used in Pandemic Preparedness and Response Overview

Dr. Tim Stenzel and **Dr. Kristian Roth** highlighted the adaptative measures, innovations, and collaborations the FDA undertook during the COVID-19 pandemic. The emphasis was on learning from these experiences to streamline processes, enhance collaboration, maintain regulatory flexibility, and improve preparedness for future pandemics.

Dr. Stenzel, Director of the Office of In Vitro Diagnostics, discussed the FDA's use of In Vitro Diagnostics (IVDs) and shared insights from COVID-19 to enhance pandemic preparedness and responses for future infectious diseases. The focus was on lessons learned, policy adaptations, and collaboration efforts from FDA. **Dr. Stenzel** provided an overview of the various pandemics and emergencies including influenza, Ebola, Zika, and COVID-19 and reviewed the authorization of IVDs under Emergency Use Authorization (EUA) during these events.

Discussing the COVID-19 Response, he highlighted FDA's swift adaptations and authorizations since the declaration of COVID-19 as a public health emergency, emphasizing the expedited policies and the issue of the first EUA authorization for a COVID diagnostic test. He explained the criteria and processes for issuing EUA, stressing that benefits outweigh known risks and the lack of adequate alternatives. He covered the evolution of FDA's COVID-19 test policy and its continuous updates to meet emerging needs and cover new developments.

Further, **Dr. Stenzel** covered new approaches and collaborations to speed up test evaluations by involving institutions like NIH and NCI and programs like ITAP.
Key points include the use of umbrella EUAs, the streamlining of authorization processes, and the study of serial testing of antigen tests to determine benefits.

Dr. Kristian Roth continued the presentation with an overview of FDA's extensive communication, outreach, and support efforts, which include webinars, FAQs, email support, and virtual town halls, to provide real-time guidance and updates to various stakeholders. He reflected on the collaborative approach with NIH and other institutions, focusing on shared learnings, variant impacts, and test evaluations.

Dr. Roth summarized the ongoing efforts for monitoring test performance against emerging variants, and the regulatory flexibility and agility demonstrated in response to changing circumstances. He described the issuance of safety communications and developer outreach concerning mutations and performance issues. Overall, he emphasized the value of regulatory flexibility and extensive engagement with internal and external partners for effective response strategies and mentioned potential strategies like prepositioning commercial developers, de-risking test development, and centralized performance validation for future pandemics.

Dr. Roth then read the FDA questions for Panel discussion.

CLARIFYING QUESTIONS FOR FDA

Dr. Van Der Pol praised the FDA's active efforts during the pandemic, especially its responsiveness and adaptation to the changing situation and its engagement with developers from the early stages of the pandemic.

Dr. Caliendo inquired about the end of the EUA and its implications. In response, **Dr. Stenzel** stated that the EUA authorities are disconnected from the declaration of the public health emergency. They can persist even after the public health emergency has ended. They end when

the secretary says they can end, and this depends on any continued needs. The availability of fully authorized tests can contribute to bringing an emergency authority to an end. **Dr. Caliendo** also asked if the FDA is required or permitted to treat some companies differently than others by regulation, like doing pre-authorization, and if that is considered anti-competitive. **Dr. Stenzel** answered that the government can plan out responses with manufacturers, and some decisions could be of a competitive nature. There may be a need for additional authorities to perform this function, and the FDA is seeking creative regulatory thinking to prepare for the next response in advance.

Dr. Petti inquired whether FDA would like the committee to stay rooted in EUA guard rails or if there will be discussion and overlap with laboratories that develop tests. Dr. Stenze answered that FDA is open for discussions regarding the needs of any test developer, and that any concerns related to home collection for Covid, or other aspects, should be brought to the FDA.

Dr. Pereira requested clarification on the legal framework governing FDA's actions during pandemics and any alterations to it post-Covid, especially regarding the FDA's engagement with the industry and its role in developing tests prior to any emergency declaration? **Dr. Stenzel** responded that FDA can lower the bar for test developers under EUA authorities, allowing them flexibility to adapt to the needs of the situation. There has been active engagement with developers whenever a need is met, even before any declarations were issued in the United States. The FDA will remain active in addressing varying needs during different phases of emergencies.

Dr. Wentzensen asked if the EUA process allows for a staged approach with an initially low bar and progressively higher demands for new tests. Further, can manufacturers be asked to update performance criteria? **Dr. Stenzel** responded: the EUA authorities do allow for progressive adjustments and additional evidence requirements. This helps in maintaining the balance in expecting and recommending evidence during emergencies. **Dr. Van Der Pol followed up:** does the FDA have the authority to rescind an EUA given to a test if it is found ineffective? **Dr. Stenzel, in response:** yes, the FDA has the authority to rescind EUAs, and some have been rescinded either at the request of the developers or voluntarily based on evaluations.

Dr. Moore requested further information on the problems with sharing data and samples and whether it involved discussions about extension of patents to coax developers back to the development table. **Dr. Stenzel** answered: sharing data related to test validation was publicly available on the FDA website. Sharing samples, especially international sharing, faced legal and logistic hurdles, requiring international agreements and funding for collaborative research posts for sample collection and sharing. As for coaxing developers, he did not provide specific information on the use of patent extensions or other incentives for developers.

Dr. Kelly inquired: should comments or suggestions be made around how to allow some flexing in the FDA staffing, like having pre-authorized reviewers who aren't employed by the FDA? In response, **Dr. Stenzel** noted that indeed, comments or suggestions on FDA staffing are valid. The FDA had to significantly expand staffing during the pandemic, utilizing funds to employ third-party reviewers and additional staff. Innovative staffing solutions and proactive planning and funding for staffing in preparation for future pandemics are under consideration.

Ms. Schwartzott wondered if FDA created a mechanism for sharing data. **Dr. Stenzel responded that** FDA was aware of data sharing mechanisms, and there was sample sharing

facilitated through collaborations, which was critical, especially for evaluating serology tests. The FDA is open to programs that facilitate data and sample sharing.

FDA QUESTIONS

Question One: How can test developers best interact with CDRH when preparing for a future pandemic? What steps can CDRH take to strengthen its communication strategies in future pandemics with test developers, laboratories performing tests, and other stakeholders such as patients and clinicians? Were any methods of communication more advantageous than others, and what might CDRH consider doing differently in future pandemics?

Dr. Van Der Pol began the responses by commenting that sometimes information made available online is not easily comprehensible by the lay user.

Dr. Blumberg advocated for FDA to make information easily accessible to practitioners and the public, emphasized the need for outreach to the lay public and inclusion of lay media, and suggested more straightforward, easily accessible, and friendly modes of communication like social media.

Mr. Spring suggested the continuation of town halls and redesigning the FDA website for easier navigation. He appreciated EU templates but advised more flexibility. He proposed the idea of public-private partnerships for planning against future pandemics, and finally encouraged better listing and accessibility to the FDA's resources.

Ms. Schwartzott recommended informational webinars for test developers and practitioners and suggested starting simple to establish the need and gradually increase the complexity of information disseminated. She advocated for more direct communication methods to make discussions more accessible and understandable.

Dr. Petti suggested incorporating more visual information, such as charts and figures, on the FDA website, advocated for the creation of standing advisory committees to gain insights from various backgrounds and industries and proposed utilizing different channels of communication, including social media, to reach wider audiences.

Dr. Van Der Pol introduced the concept of "Digital Champions" to help in forwarding content within networks and emphasized the importance of improving outreach efforts and finding innovative solutions to communicate with a diverse range of audiences.

Dr. Stenzel noted that FDA does social media and email blasts and has added search functions and graphic functionalities to aid comprehension of information and its accessibility.

Dr. Pereira highlighted the importance of engaging communication officers who can distill and communicate complex information to the public effectively, underlined the necessity of maintaining creativity and flexibility in preparing for unforeseeable future pandemics. He expressed interest in the FDA's participation in simulation games and other preparatory activities for unforeseen pandemics and asked if these were currently implemented; **Dr. Stenzel** provided details on inter-agency collaboration efforts for preparedness.

Dr. Walker advocated for more creative, engaging, and consumer-friendly communications, particularly through digital and social media platforms. Stressed the importance of effective communication in combating misinformation and in reaching diverse communities.

Dr. Caliendo emphasized the importance of coordinated communication between FDA and CDC to provide aligned, clear, and coherent messages to the public and pointed out the scattered nature of messages received and emphasized the importance of unified messaging.

Dr. Honein from CDC commended FDA's communication efforts but encouraged reaching audiences outside the usual community. She recommended coordinated presentation between CDC and FDA and utilizing existing calls with public health officials to further amplify messages.

Dr. Stenzel responded to several comments, clarifying FDA's communication roles and procedures, the FDA's collaborative efforts with CDC, and their focus on enhancing their communication strategy. He discussed coordination and communication with CDC and other agencies, mentioning regular meetings with various high-level representatives from different agencies and organizations. He spoke on the participation in CDC lab calls and state epidemiology calls and his efforts in addressing questions in various meetings related to testing coordination. He highlighted the challenges with ensuring consistent information while dealing with numerous inquiries from multiple manufacturers and discussed the FDA's early engagement and preparedness for various potential threats like Mpox and Ebola and the Agency's ongoing vigilance in monitoring potential threats.

Dr. Ng praised the FDA website from a clinical laboratory perspective, describing it as a beacon of truth for identifying tests, citing its constant updates. She commented on the CDC's laboratory outreach communication system and how it provided a platform for discussions early on in the pandemic. She discussed the roles of clinical laboratories in communication and how they liaise with different stakeholders, emphasizing the importance of partnerships for effective message delivery. She encouraged the group to explore their roles in communication and urged the strengthening of partnerships for more effective messaging to the community.

Dr. Van Der Pol suggested that members of the meeting could serve as ambassadors, helping to promote the FDA and its resources in the community. She emphasized the importance of inviting FDA representatives to speak at meetings and events to enhance understanding of FDA processes and rationales.

Dr. Van Der Pol then summarized the panel discussion, recapping the suggestions and discussions on enhancing communication strategies and interaction mechanisms, highlighting the transparency and the usefulness of the information provided by the FDA during the pandemic. Key points included improving the website interaction mechanisms, working with lay media, implementing digital outreach strategies and alternate learning mechanisms such as graphics without losing text entirely, involving standing advisory committees. The usefulness of town halls, webinars, telephone lines, national scientific meetings, and EUA templates was highlighted. The suggestion was brought forth that FDA should provide clear instructions on how to access information and how to develop studies and documentations, for the aid of both manufacturers and the lay public. The Panel also found helpful the idea of advance preparation and regular meetings of public-private collaborations and specific government task forces for emergency preparedness.

Dr. Petti asked if developers had sufficient resources to engage with FDA to immediately start test development processes. **Mr. Spring** responded affirmatively; **Dr. Stenzel** provided more details on staffing and FDA efforts to keep lines open to developers.

Dr. Van Der Pol specifically requested that the consensus of the Panel that FDA's efforts to respond to Covid in a timely manner were greatly appreciated. She added that the public needs to know that FDA is going to such lengths. To this point, **Dr. Wentzensen** added that messaging about FDA alert system is buried on the website and should be more visible. **Dr. Moore** echoed this. **Dr. Kotton** also suggested more positive public information, which **Dr. Van Der Pol** seconded as imperative to the public understanding the extensiveness of FDA's involvement.

Question Two: What types of educational resources or communications from CDRH would be most valuable to aid test developers with respect to test development in preparation for a future pandemic?

Dr. Ng explored the idea of developing a structured plan for scalability. She suggested that educational resources should address the challenges faced by test developers in scaling up production to meet demand during a pandemic.

Dr. Stenzel reflected on the efforts made during the pandemic regarding throughput manufacturing and the prioritization of high throughput and high volume test manufacturers. He highlighted the financial resources made available for scaling up production, emphasizing the success of these efforts. He stressed the importance of identifying appropriate manufacturers and test types for cooperation and support. He also mentioned the efforts and programs FDA already has in place for education and collaboration and stressed the potential for improvement and wider dissemination of existing educational resources.

Dr. Petti mentioned the importance of creating EUA templates for emerging test developers to help them understand what a pandemic scenario would look like. She proposed the creation of a guide on the FDA website which could serve as a reference for test developers in preparing for future pandemics, helping them understand the evolution of prioritization and other elements of pandemic response. She also pointed out the importance of communication about potential expectations and emphasized the need for educating new test developers about analytical validation and different matrices.

Dr. Van Der Pol emphasized that educational documents about scaling would be useful for test developers and voiced concerns over specificity and sensitivity of tests in different use case scenarios, specifically referencing mass events like football games.

Mr. Spring agreed with Dr. Van Der Pol's points and extended the concern to daily challenges faced by diagnostic manufacturers and developers. He recommended the development of educational resources involving experts in various fields to provide upfront challenges and required considerations before submissions to the FDA, thereby facilitating the validation of new technologies.

Dr. Van Der Pol summarized the Panel's contributions. In general, there was appreciation for templates like the EUA templates. The Panel would find it useful to ensure that examples from the Covid process are made available to people. Transparent descriptions of processes for prioritization would be helpful for developer knowledge. Documents describing the

requirements for scaling and for proving LOD or LOQ against pre-created panels of pathogens would also be useful for developers. And finally, educational materials are desired to aid thinking about use case scenarios.

Question Three: Are there certain types of instrument/test component manufacturers with whom CDRH should collaborate in preparation for a future pandemic response to ensure test availability in a future pandemic?

Dr. Van Der Pol initiated the discussion, emphasizing collaboration between CDRH and instrument/test component manufacturers. She identified collection devices and universal transport media as critical components, emphasizing their scarcity during the pandemic. She also discussed the need for prioritizing high-throughput instruments capable of both molecular and serology tests.

Dr. Caliendo emphasized the need for diversity in test types and platform variety to meet different needs at various pandemic stages. She questioned the practicality and efficiency of FDA interactions with numerous companies, emphasizing the importance of prioritizing impactful collaborations. She further emphasized the importance of having the ability to test within institutions and the necessity of preparing for supply chain disruptions.

Dr. Stenzel raised questions about the relevance and timing of different tests during various pandemic phases, discussing the development and deployment challenges of each. He underlined the importance of considering different tests' needs at different pandemic stages. **Dr. Caliendo,** in response to this inquiry, discussed the primary importance of molecular tests, especially in the early stages of an outbreak, questioning the practical value of early serologic testing. She suggested preparation for diverse pathogens and emphasized the importance of molecular tests in managing them. **Dr. Van Der Pol** continued by highlighting the need for instruments capable of covering a wide spectrum of tests and advocated for preparedness plans focusing on standardized high-throughput instruments and those with user-defined capacities. **Dr. Stenzel** finished these thoughts by highlighting the necessity of high-throughput systems and emphasized preparation for utilizing available systems and technologies and emphasizing the importance of planning and preparation to avoid delays in deploying high-throughput automated systems during emergencies.

Dr. Petti highlighted the need for early FDA guidance for high-throughput systems. She discussed the failure points during the pandemic, including staff shortages and logistical challenges in small community-based hospitals. She suggested exploring novel instrument requirements and distributed high-throughput solutions using existing technologies in various settings, emphasizing early planning with agencies like BARDA.

Mr. Spring suggested a landscape analysis of available systems and their capabilities. He further suggested enabling manufacturers to work directly with laboratories for test development during emergencies. He posed questions regarding prioritization and suggested convening expert groups and conducting scenario analysis to determine future needs and focus areas.

Dr. Honein emphasized the importance of utilizing the public health laboratory network early in a response and ensuring that their needs are prioritized in preparedness plans and stressed the importance of redundancy and having multiple options to circumvent supply chain issues. **Dr. Stenzel** specified the ongoing efforts and interactions with public health labs and stressed the importance of redundancy and preparation.

Dr. Caliendo supported the idea of pre-authorization of labs and highlighted the need for a diverse array of platforms. She discussed the potential of having FDA-preapproved primer pairs and protocols on diverse platforms to facilitate rapid test deployment. **Dr. Van Der Pol** continued this thought and covered the relevance of instrument-focused pre-authorization and the importance of having versatile, high-throughput systems with open channels for various tests. She also discussed the need for flexibility and adaptability in test platforms to accommodate different needs and scenarios.

Dr. Ng differentiated between centralized and distributed models of testing, pointing out the issues with each, including logistical and bureaucratic challenges and the need for informatics support. She discussed the constraints and challenges faced by smaller labs and public health labs due to regulatory and staffing issues. She emphasized the importance of developing and enhancing logistical and informatics infrastructures to support efficient testing and result reporting. **Dr. Van Der Pol** and **Dr. Ng** discussed the regulatory constraints faced by labs and suggested the need for flexible regulatory approaches during pandemics, allowing for the circumvention of certain procedural constraints while maintaining quality and safety standards. **Dr. Stenzel** commented here that the collaborative efforts with other agencies like CMS during the pandemic and the allowances made to facilitate testing and response.

Dr. Caliendo agreed with Dr. Ng on the varying needs of different labs and emphasized the importance of diversity in testing approaches and platforms. She suggested advanced planning and coordination with CDC to validate and standardize tests on different platforms for quick deployment during emergencies.

Dr. Pereira emphasized the necessity of planning for diverse test types including serologies and antigen testing for different pandemics. Suggested focusing on rapid development of tests including ones identifying immune and non-immune populations.

Dr. Kotton advocated for testing equity and affordability, considering the rural populations and those far from academic institutions. He highlighted the disparities and inequities in access to diagnostics during the pandemic. He queried about who sets pricing on tests and noted a perceived existence of predatory pricing behaviors.

Dr. Stenzel responded by reiterating the importance of equity across different locations, populations, and sites and the significant role of cost. He emphasized the potential of readily deployable, universal pathogen tests and the need for stockpiling authorized tests for readiness. He addressed concerns about user ability and comprehension in usability testing, acknowledging the limitations due to the urgency of pandemic response. He stated that FDA does not have a role in pricing or reimbursement but can prioritize technologies that are lower cost.

Ms. Schwartzott expressed concerns about the clarity and comprehensibility of packaging, labeling, and instructions of test kits. She shared personal experiences of confusion and lack of proper knowledge among medical professionals regarding the use of test kits early in the pandemic. She recommended involving laypersons in creating user-friendly instructions and addressing these concerns preemptively. **Dr. Van Der Pol** agreed with Ms. Schwartzott, and she pointed out the usual recruitment of more educated, self-selected individuals for usability studies, underscoring the need for independent reviews by end users with varying levels of understanding. She also addressed the need for prioritizing devices with approved self-collected samples and to consider the outreach capabilities of different types of tests.

Dr. La Hoz next reminded the need to be prepared for different types of pathogens and to consider the nuances of testing in different types of samples. He highlighted the importance of developing tests keeping in mind the immunocompromised patients and those at risk for complications.

Dr. Ng addressed previous comments from multiple Panelists in her next response. She addressed the misconceptions around antibody testing and the limitations of such tests in informing about immunity. She talked about the access problems in communities impacted disproportionately by COVID and emphasized the necessity of community outreach. She suggested consideration for populations with language barriers and emphasized the importance of picture-based instructions or verbal guidance.

Dr. Pereira clarified that his initial comment was more in line with keeping an open mind for future pandemics and not strictly about serology testing for SARS-CoV-2. He further mentioned the consideration for pediatric populations, especially neonates, in test development due to varied requirements.

Dr. Blumberg emphasized the power and importance of bringing diverse testing to the community and the consideration of equity in community outreach. She highlighted the impact of COVID in teaching the importance of community-based testing and its potential diversity in future.

Dr. Kotton asked if FDA gives guidance on pricing. **Dr. Stenzel** responded that FDA will prioritize lower-cost technologies in emergency situations. In this context, **Mr. Spring** spoke about considering equity in prioritizing technologies and encouraged the inclusion of products available outside the U.S. through the EUA process to fill gaps in specimen collection. **Dr. Pereira** added that the needs of children and specific vulnerable populations should be kept in mind if their specimens are desired.

Dr. Roth sought more information about the specific aspects of home tests that users found unclear or difficult to interpret and execute. **Dr. Van Der Pol**, in response to this, shared her experiences in equity and outreach, describing the challenges encountered when changing tests. She emphasized the need for clear, concise, picture-based instructions to improve user understanding and execution of tests.

Ms. Schwartzott cited examples of personal experiences to illustrate difficulties and misdirection experienced with the available testing kits. She mentioned that there were issues with the test's directions, confusing app integrations, and ineffective or incorrect testing methods. She highlighted the critical need for proper instructions and accessibility for people with disabilities. She addressed the misinformation and confusion prevalent among the public, advocating for clearer and simplified information. She also recommended collaboration with organizations serving people with disabilities and communities with disparities to create comprehensive guidelines. Along these lines, **Dr. Roth** mentioned the importance of visual instructions and realistic images on the kits to aid understanding. **Dr. Stenzel** talked about an NIH funded effort to create universal videos for home tests. He discussed the variations in test workflows and suggested presetting types of technologies and specific manufacturers to standardize workflow and design to accommodate diverse user needs. He proposed independent usability measurements and recommendations to make tests user-friendly and accessible and stressed the importance of fair dealings with all developers.

Continuing on this point, **Dr. Van Der Pol** suggested a review process involving actual end-users for creating user-friendly instructions. She talked about creating guidance for test instructions that incorporates equity and diversity considerations. She mentioned the necessity for research and considerations for varying user needs. **Dr. Roth** talked about the stylized look of the directions and the need for more realistic images to aid understanding. **Dr. Wentzensen** suggested staged approaches for user testing and guidance creation to improve usability over time, keeping initial entry barriers low.

Mr. Spring emphasized the industry's willingness to improve test usability and accuracy. He mentioned existing human factors programs at FDA to look into human factor studies, pointing out the need for considering global use and cultural differences in test design and usage instructions. He stressed the importance of making tests easy for diverse user groups and settings.

Dr. Van Der Pol summarized the discussion. There is a need for a mechanism to prioritize test components and types of tests to avoid dealing with a plethora of applications and to ensure only the most useful tests reach the market. There is a need for broad coverage and diversity in types of mechanisms to avoid dependence on one manufacturer or type of test. It is important to utilize high-throughput systems that had open channel access, especially those useful in emergency situations, to help individual labs develop or optimize tests quickly. CDC involvement was recommended for validating and optimizing the first line of primers and probes on various platforms. Equity concerns were broached; affordable, accessible, and stable solutions should be prioritized. Platforms that can handle diverse sample types should be prioritized, and those with diverse needs such as children and immunocompromised persons should be considered specifically. There was reminder to keep biological plausibility in mind when evaluating new testing concepts or solutions. User-friendly instructions are paramount and end users should give feedback during the review process. Pre-authorization is an important consideration to help understand how rapid mobilization can be achieved. **Dr. Stenzel** brought up

the Yale saliva test as a template protocol for diagnostics, lauding it as an appropriate solution that could be applied to other arenas. **Dr. Van Der Pol** concurred.

Question Four: Are there certain types of tests or developers that should be prioritized for review in the early stages of a future pandemic?

Dr. Van Der Pol deemed this question largely already answered and prompted any further comments.

Mr. Spring added that perhaps the first-in, first-out approach to fielding thousands of requests from developers may not been in FDA's best interest, and prioritization criteria should be considered in conjunction with an initial sense of quality of the submission to determine which approvals to fast track.

Dr. Stenzel gave details on how FDA prioritized the review of Covid tests, noting that it increased efficiency and asking the Panel if this was a well-directed effort.

Dr. Petti noted that manufacturers with specific protocols for data reporting to agencies and healthcare providers should be prioritized. **Dr. Van Der Pol** concurred and added that FDA should work with CDC to develop uniform and streamlined reporting processes for manufacturers. **Dr. Stenzel** provided further details on reporting processes and challenges.

Dr. Van Der Pol summarized the Panel's contributions to Question Four between this section and the last. Prioritization based on test type is ideal, but the Panel did not identify a specific test type that should be prioritized. The Panel would like to see FDA ready to review all test types in event of a pandemic. Quality of the submission, regulatory experience of the sponsor, and device connectivity and reporting could factor into the prioritization.

Question Five: What are the key features of tests or certain test designs that would be helpful in a future pandemic?

Dr. Van Der Pol stressed the importance of high-throughput tests, user-friendly tests, and tests that can address equity, inclusivity, and diversity concerns. She suggested having tests that use either a dry sample, an unadulterated sample, or something in a universal transport buffer for flexibility across different platforms. She mentioned that manufacturers with viable solutions for molecular diagnostics should be prioritized. She addressed the necessity to include pregnant women in research and studies for designing tests.

Dr. Caliendo discussed a missed opportunity to assess agreement across different tests due to a lack of standardization and suggested the FDA require testing and reporting in international units. She addressed the importance of being proactive and having secondary standards ready ahead of the next pandemic and mentioned the need for the feedback from companies regarding the compatibility of materials sent out by the FDA.

Dr. Stenzel addressed the challenges with international standards and the distribution of materials and emphasized the importance of making advancements in reference materials. He discussed the difficulties and limitations related to CT values in reporting results and emphasized the agency's openness to new ideas supported by science and data. He mentioned the Agency's willingness and openness to submissions related to different types of tests, especially those related to monitoring disease and resolving prognosis. **Dr. Scherf a**greed with Dr. Caliendo on the need for standardized testing material but highlighted the limitations faced in acquiring enough international standards from WHO for widespread study and assessment. He further addressed the importance of obtaining feedback and improving standards and materials provided.

Dr. Pereira emphasized the importance of test sensitivity and specificity in different populations, including pediatrics and immunocompromised patients. He addressed the need for tests capable of monitoring disease progression and resolving infections, which would help in managing isolations and treatment approaches.

Mr. Spring commented on the restrictions in reporting out CT values during the EUA process and how access to these might be limited in the future.

Dr. La Hoz emphasized the heterogeneity within the immunocompromised host group and the importance of developing infectivity assays to address specific needs in transplantations and to manage organ donations effectively during pandemics.

Dr. Van Der Pol summarized the contributions to Question Five**.** She stressed the importance of universal transport, well-standardized panels for LODs comparison across platforms, the necessity for sensitivity and specificity in test designs to include varied populations like pediatrics, pregnant women, and immunocompromised individuals from different backgrounds, and the potential benefits of tests capable of quantification or viability assessment for monitoring disease status along with infection status.

Question Six: What other lessons from the recent COVID-19 pandemic and Mpox emergencies might CDRH take into consideration in preparing for future pandemics?

Dr. Van Der Pol emphasized the importance of clear and quick information sheets for point-of-care and over-the-counter tests. She proposed using COVID EUA packets as a template for future submissions and highlighted the necessity of using the pre-EUA process for early feedback in the developmental and design process.

Dr. Honein discussed challenges and variation due to ramping up and adding new reviewers to the process during a pandemic, and the need for consistent training and familiarity with FDA processes for new reviewers.

Dr. Blumberg stressed the need for testing platforms with access for vulnerable populations and lower-resource individuals, emphasizing simplicity and accessibility.

Dr. Petti suggested potential legislation to allow FDA a pre-approved resource increase during pandemics. She mentioned the possibility of utilizing a reserve of retired reviewers or experienced individuals to aid in submission reviews during high-demand times.

Dr. Van Der Pol and **Dr. Petti** discussed the idea of having pre-vetted individuals who could act as external reviewers, somewhat like an NIH study session, reviewing the science, the data, and the usability aspects.

Dr. Ng urged reconsideration of dry ice transport requirements due to availability issues. **Dr. Stenzel** clarified that the FDA never made such a requirement.

Dr. Caliendo highlighted the utility of having contracted groups available for reviews, having them screened, and ready to roll when needed. She mentioned the willingness of professionals to volunteer their time and expertise during crises, and the Panel agreed. **Dr. Van Der Pol** added that the time to train people to do these things is now. **Dr.** Spring, towards this point, suggested the use of a pool of available reviewers to review previous 510Ks or EUAs as a refresher and to maintain familiarity with FDA processes and expectations.

Dr. Kotton inquired about existing SOPs and preparedness plans to ensure smoother responses in future pandemics. In response, **Dr. Stenzel** responded that SOPs are in place and discussed the accumulated experience from past emergencies and the ongoing efforts to refine response mechanisms, emphasizing the scale of the pandemic impacts response structures, mentioning the continuous work and interactions with various entities to prepare for future emergencies.

Dr. Van Der Pol summarized the Panel's recommendations. There was a call for the development of SOPs, guidelines, and templates based on successful strategies from past responses, ensuring consistent and clear review processes. The Panel perceives a necessity for considering and prioritizing products and assays that provide accessibility to the most vulnerable and marginalized populations was emphasized. Proactive legislative measures should be implemented, as well as resource planning and mobilization of a pool of expert reviewers to ensure preparedness and effective response in future pandemics. Logistic constraints, such as the need for dry ice, should be avoided. Experts are willing to volunteer their services to aid pandemic preparedness. The Panel finally suggested maintaining the familiarity of pre-vetted external reviewers with FDA processes]to handling increased review demands during emergencies.

CLOSING COMMENTS

Dr. Walker, **Dr. Spring**, and **Ms. Schwartzott** all expressed that they found today's conversation interesting and informative and thanked the Panelists and FDA. **Ms. Schwartzott** emphasized the importance of transparency between the FDA and Public, noting transparency is facilitated by this meeting.

Dr. Stenzel thanked the Panel, FDA representatives, and public attendees and underscored the success and usefulness of the Advisory Committee Meeting.

Dr. Moore added that the biggest unmet need in the arena of emergency preparedness is in the arena of CDC and other government entities, but FDA has a direct and important role to play in conveying information about problems to the public.

ADJOURNMENT

Dr. Van Der Pol thanked the Panelists, FDA, and speakers and adjourned the meeting.

I approve the minutes of this meeting as recorded in this summary.

Barbara Van Der Pol, Ph.D., M.P.H.
Chairperson

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September 27, 2023

I certify that I attended this meeting on September 8, 2023 and that these minutes accurately reflect what transpired

Candace J. Nalls -S

Digitally signed by Candace J. Nalls -S
Date: 2023.10.02 12:08:01 -04'00'

Candace Nalls
Designated Federal Officer